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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,480	12/13/2004	Hudson Freeze	UCSD-08831	4479

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT	PAPER NUMBER
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1653

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11/06/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,480	Applicant(s) FREEZE ET AL.	
	Examiner SHERIDAN MACAULEY	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 136, 144-152, 154, 155, 157-159, 162-164 and 170-176 is/are pending in the application.
- 4a) Of the above claim(s) 144-152, 154, 155, 157-159 and 162-164 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 136 and 170-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on March 1, 2012 and October 6, 2011 have been received and entered. All evidence and arguments have been fully considered. Claims 136, 144-152, 154, 155, 157-159, 162-164 and 170-176 are pending. Claims 144-152, 154, 155, 157-159 and 162-164 are withdrawn from consideration due to a previous requirement for restriction/election. Claims 136 and 170-176, insofar as they read upon the elected species, are examined on the merits in this Office action.

Declaration under 37 CFR 1.132

1. The declaration under 37 CFR 1.132 filed October 6, 2011 is sufficient to overcome the rejection of claims 136 and 170-176 based under 35 USC 112, first paragraph as set forth in the last Office action.

Claim Rejections - 35 USC § 112

2. Rejections under 35 USC 112, second paragraph have been withdrawn due to amendment.
3. Rejections of claims 167-169 under 35 USC 112, first paragraph have been withdrawn due to amendment.
4. Rejections of claims 136 and 170-176 under 35 USC 112, first paragraph have been withdrawn due to applicant's arguments (see declaration under 37 CFR 1.132 filed October 6, 2011).

Claim Rejections - 35 USC § 103

5. Rejections under 35 USC 103 have been withdrawn due to amendment.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 136 and 170-176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varki et al. (US 5,449,781), Stern et al. (US 2002/0122799 A1) and

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Hodges et al. (US 5,738,996), as evidenced by Turovskaya (Carcinogenesis, 29:2035-2043).

10. Varki teaches a method for screening test agents (proteins) using purified BAP-conjugated glycans (saccharides) to identify agents that bind to the glycans (col. 7, lines 17-25, col. 9, example 3). Varki teaches that purified glycans may be produced by conjugating a molecule that comprises a carboxylated glycan (e.g., those containing siacylic acid residues) with BAP to produce a BAP-glycan conjugate, treating the BAP-glycan conjugate with an exoglycosidase (sialidase), and isolating the BAP-glycan conjugate, thereby producing a purified glycan (col. 9, line 51-col. 10, line 8, col. 10, lines 47-62). Varki teaches that the molecule which comprises the glycan can be a polysaccharide or glycoprotein (col. 1, lines 48-59, col. 9, line 66-col. 10, line 8). Although Varki does not specifically teach that the BAP-glycan conjugate has 1 to 2 negative charges per molecule, the process may be used to produce a number of conjugates that would inherently have the claimed charges. Varki teaches that antibodies may be produced which specifically bind to the purified glycans (col. 7. lines 8-13).

11. Varki does not teach identifying the test agent as reducing inflammation in a tissue. The reference does not specifically teach the use of a carboxylated glycan that binds to S100A, S100A9, S10012, amphoterin or annexin I. The reference does not teach the use of an antibody in the method for screening test agents.

12. Stern teaches a method of identifying a test agent as reducing inflammation in a tissue (abstract, p. 12, par. 122). The reference teaches that molecules that bind with

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the receptor for advance glycation endproducts (RAGE) glycoprotein may be identified as reducing inflammation (p. 3, par. 33). The reference teaches that RAGE interacts with S100/calgranulins (p. 21, par. 295; note that calgranulins comprise three proteins: S100A8, S100A9 and S10012) and amphoterin (p. 17, par. 243). Stern teaches the administration of the test agents to a mouse having inflammation in a tissue and detecting a reduction in inflammation in the presence of the test agent (p. 12, par. 124-127).

13. Hodges teaches a method for identifying a test agent as binding to an antigen wherein a labeled antigen is bound to an antibody and a test agent, wherein the reduction of the level of binding of the antibody to the antigen is detected and is indicative of specific binding of the test agent to the antigen (col. 13, lines 28-44, col. 14, lines 6-15).

14. At the time of the invention, a method of identifying test agents comprising nearly all of the claimed elements was known, as taught by Varki. It was further known that test agents that may reduce inflammation could be identified based upon their ability to bind with the RAGE protein, which interacts with S100/calgranulins and amphoterin, as taught by Stern. One of ordinary skill in the art would have been motivated to combine these teachings because Varki teaches that it would be desirable to produce BAP conjugates with glycoproteins as well as oligosaccharides (col. 1, lines 48-59), and RAGE was a known glycoprotein at the time of the invention. One of ordinary skill in the art would therefore have recognized that the methods of Varki could have been advantageously used with the RAGE protein taught by Stern. Glycans purified from

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RAGE would also inherently bind to S100/calgranulins, amphoterin, annexin I or a portion of annexin I, as evidenced by Turovskaya, who teaches that glycans bound to RAGE bind to these protein (p. 2035, col. 2, par. 2). One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because Varki teaches that the process may be used to purify any molecule with a bound glycan, such as RAGE.

15. One of ordinary skill in the art would further have been motivated to use the antibody binding methods of Hodges because Varki teaches that it would be desirable to use the screening method taught therein to screen for proteins that bind to saccharides (col. 7, lines 18-21). Hodges teaches a method of using antibodies to screen for proteins that bind to an antigen. One of ordinary skill in the art would therefore have recognized that it would be desirable to use the methods of Hodges in combination with the method taught by Varki. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because Varki teaches all of the required elements and Hodges teaches simplified screening methods. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

16. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

17. Applicant's arguments, see section 5 of the response filed October 6, 2011, with respect to the rejection(s) of claim(s) 136 and 167-176 under 35 USC 112, first paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Varki et al. (US 5,449,781), Stern et al. (US 2002/0122799 A1) and Hodges et al. (US 5,738,996), as evidenced by Turovskaya (Carcinogenesis, 29:2035-2043), as set forth above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/SHARMILA G. LANDAU/

Supervisory Patent Examiner, Art Unit 1653